

inflammation of the kidneys, pain in the kidneys, prolapsed kidneys, cirrhosis of the liver, pain in the liver, locomotor ataxia, lumbago, hemorrhage of the lungs, excessive menstruation, painful menstruation, suppression of menstruation, nephritis, neurasthenia, nosebleed, congestion of the ovaries, pertussis, piles, heart weakness in pneumonia, poliomyelitis, pain in the prostate gland, pulmonary atelectasis, pain in the rectum, chronic catarrh of the sinuses, splachnoptosis, enlarged spleen in progressive anemia, pain in the spleen, pain in the stomach, prolapsed stomach, sunstroke, incontinence of urine, pain in the uterus and appendages, subinvolution of the uterus and appendages, vasomotor paralysis, vasomotor spasm, congested viscera, whooping cough, ankylosis, adhesions, generalized atonia, indolent liver and gallbladder, and excess fat. The device would not provide an adequate and effective treatment for such conditions.

The devices were misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: No claimant having appeared, the court entered a decree of condemnation against the *Pedazine devices* on April 7, 1953, and a decree of condemnation against the other devices on July 14, 1953. The court ordered that the devices and their labeling be delivered to the Food and Drug Administration.

DRUGS FOR VETERINARY USE

✓ 4239. Misbranding of Blake's Mineral Compound. U. S. v. 14 Bags, etc. Motion for summary judgment granted. Decree of condemnation. (F. D. C. No. 33292. Sample Nos. 13531-L, 13532-L.)

LABEL FILED: June 16, 1952, District of Idaho.

ALLEGED SHIPMENT: On or about October 4 and 11, 1951, and March 3, 1952, the Hy-Life Mineral Co. shipped from Denver, Colo., a number of 105-pound bags of a mineral compound.

PRODUCT: 14 105-pound bags of a mineral compound, 5 cartons of *Blake's Mineral Compound*, and 550 empty cartons in possession of the Globe Seed & Feed Co., Inc., at Twin Falls, Idaho.

RESULTS OF INVESTIGATION: The product contained in the cartons had been repackaged from a portion of a bulk shipment described above. The empty cartons were to be filled with an additional quantity of the product contained from the bulk shipment. All of the cartons had been printed for the consignee in Denver, Colo.

LABEL, IN PART: (Tag) "Hy-Life Mineral Co. Manufacturers of Chemical Products For Livestock Men 2145 Blake Street Denver, Colo."; (bag) "Mineral Compound 105 Lbs. Net."; (carton) "Blake's Mineral Compound * * * Ingredients: (Active) Ammonium Chloride; Potassium Chlorate; Sodium Sulphate; Calcium Carbonate; Tobacco Powder. Red Oxide of Iron is added as a coloring agent * * * Oil of Anise Added * * * Net contents—3½ lbs. Manufactured by Banner Mills Operated by Globe Seed & Feed Co., Inc. Twin Falls, Idaho."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the carton label were false and misleading since the statements represented and suggested that the article was effective in the prevention and treatment of bloat in sheep and cattle, whereas the article was not effective for such purposes: "A chemical preparation which, when mixed with salt as directed, is designed for feeding Sheep and Cattle while pasturing in green Alfalfa, Clover or in

Corn and Wheat fields. * * * 1. Mix entire contents of this package (3½ lbs.) with 100 lbs. of finely ground salt. * * * Remove all other salt from your livestock. Place this mixture in troughs conveniently accessible to livestock. Note: Feed above mixture to livestock for several days before turning them into green pastures and constantly thereafter."

Further misbranding, Section 502 (a), the name of the article "Blake's Mineral Compound" and the representations on the label that the declared ingredients were active, coupled with the directions for use, namely, "1. Mix entire contents of this package (3½ lbs.) with 100 lbs. of finely ground salt. * * * Remove all other salt from your livestock. Place this mixture in troughs conveniently accessible to livestock. Note: Feed above mixture to livestock for several days before turning them into green pastures and constantly thereafter. 2. When grain is fed—for example, to dairy cows—mix one 3½ lb. package of Blake's Mineral Compound with only 15 lbs. of finely ground salt. Use this mixture to season the grain. Allow from one to two level tablespoons per head for cattle, or two level teaspoons per head for sheep. In addition to treating the grain ration when one is fed, be certain also to have the mixture described in paragraph one (above) available in troughs," were false and misleading. Such name and representations suggested that the article furnished essential minerals required by sheep and cattle, whereas, ammonium chloride and sodium sulfate, two of the declared active ingredients, are not required by sheep and cattle; and tobacco powder is not a mineral, and, when used as directed, the article furnished inconsequential nutritional amounts of potassium chlorate and calcium carbonate, the two other declared active ingredients.

Further misbranding, Section 502 (a), the statement "Manufactured by Banner Mills Operated by Globe Seed & Feed Co., Inc. Twin Falls, Idaho" appearing on the carton label was false and misleading since the article was not manufactured by Globe Seed & Feed Co., Inc., nor at Twin Falls, Idaho; and Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

The article was misbranded under Section 502 (a) while held for sale after shipment in interstate commerce and under Section 502 (f) (1) when introduced into and while in interstate commerce.

DISPOSITION: The Hy-Life Mineral Co., J. P. Rosenbaum & Co., and Globe Seed & Feed Co., Inc., appeared as joint claimants and filed an answer denying that the product was misbranded. A motion for summary judgment was filed by the Government on November 13, 1952. On March 24, 1953, after considering the briefs and arguments of counsel, the court granted the motion for summary judgement, and on April 7, 1953, handed down the following findings of fact and conclusions of law:

CLARK, District Judge: "This cause having come on for hearing on the plaintiff's motion for summary judgment, the Court, after hearing oral argument and considering the pleadings, affidavits, and memoranda submitted by counsel for both parties, hereby makes the following findings of fact and conclusions of law:

FINDINGS OF FACT

"1. The article seized in this action consisted of a number of 105# bags of a mineral compound, the main ingredients of which are ammonium chloride, potassium chlorate, sodium sulfate, calcium carbonate, and tobacco powder.

"2. The seized article was shipped in interstate commerce by the Hy-Life Mineral Company from Denver, Colorado, to Globe Seed & Feed Company, Inc., Twin Falls, Idaho, on or about October 4 and 11, 1951, and March 3, 1952.

"3. When introduced into and while in interstate commerce the labeling of the article consisted of the following written, printed, and graphic matter:

(Tag) Hy-Life Mineral Co. Manufacturers
of Chemical Products For Livestock
Men 2145 Blake Street Denver, Colo.
(Bag) Mineral Compound 105 Lbs. Net

"4. The article was intended for use in the treatment of bloat in sheep and cattle.

"5. When introduced into and while in interstate commerce the labeling of the article did not state that the article was intended to treat 'bloat,' nor did it bear any directions for use in the treatment of that disease.

"6. While held for sale by the Globe Seed & Feed Company, Inc., at Twin Falls, Idaho, after shipment in interstate commerce, the article was accompanied by labeling which read, in part, as follows:

(Carton) Blake's MINERAL COMPOUND

A chemical preparation which, when mixed with salt as directed, is designed for feeding Sheep and Cattle while pasturing in green Alfalfa, Clover or in Corn and Wheat fields.

INGREDIENTS: (Active) Ammonium Chloride;
Potassium Chlorate; Sodium Sulphate;
Calcium Carbonate; Tobacco Powder.

Red Oxide of Iron is added as a coloring agent * * * Oil of Anise added * * * Net contents—3½ lbs. Manufactured by Banner Mills Operated by Globe Seed & Feed Co., Inc., Twin Falls, Idaho.

1. Mix entire contents of this package (3½ lbs.) with 100 lbs. of finely ground salt. * * * REMOVE ALL OTHER SALT FROM YOUR LIVESTOCK. Place this mixture in troughs conveniently accessible to livestock.

Note: Feed above mixture to livestock for several days before turning them into green pastures and constantly thereafter.

These statements suggest and imply that the article is effective in the prevention and treatment of bloat in sheep and cattle.

"7. The claimants in this action are the Hy-Life Mineral Company, J. P. Rosenbaum, owner of the Hy-Life Mineral Company, and the Globe Seed & Feed Company, Inc., a corporation.

"8. The Hy-Life Mineral Company and J. P. Rosenbaum, its owner, shipped the seized article in interstate commerce. The Globe Seed & Feed Company, Inc., obtained all right, title, and interest to the article through purchase from the Hy-Life Mineral Company and J. P. Rosenbaum.

"9. In 1945 a seizure action was brought against a quantity of this same article under the name of 'Blake's Stop-Bloat Chemicals' in the United States District Court for the District of Wyoming. It was alleged that the product was misbranded in that it was represented in its labeling as being effective when used as directed in preventing bloat in livestock. These representations were alleged to be false and misleading in that the article would not prevent bloat in livestock. While the claims of preventing bloat were stated in different language in the labeling involved in the 1945 seizure action, the impression made was substantially the same as that conveyed by the labeling involved in the present proceeding, namely, that the article would prevent bloat in livestock. The article involved in the seizure action in the United States District Court for the District of Wyoming consisted essentially of the same ingredients as the article herein seized, although minor quantitative differences exist in the ingredients present. The action of the article when fed to livestock would not be changed by these minor quantitative differences. After trial without a jury, the United States District Court for the District of Wyoming found that the article would not mitigate, treat, cure, or prevent bloat

in livestock and found as a matter of law that the article was misbranded. The Court entered a decree of condemnation and ordered that the seized article be destroyed. This action was No. 2960 Civil, decided March 11, 1946.

"10. The claimant in this proceeding, J. P. Rosenbaum, the owner of the Hy-Life Mineral Company, appeared as claimant and contested the previous action decided in the United States District Court for the District of Wyoming.

"11. Subsequent actions were filed against other shipments of the article involved in this action in 1945 in the United States District Court for the District of Kansas, First Division, Civil Action No. 5366; in 1945 in the United States District Court for the District of Montana, Butte Division; and three other seizure actions in the District of New Mexico in May of 1952, Nos. 2048, 2049, and 2050. All of these actions resulted in default decrees of condemnation.

CONCLUSIONS OF LAW

"On the basis of the foregoing findings of fact, I hereby conclude as a matter of law:

"1. The seized article is a drug within the meaning of 21 U. S. C. 321 (g) (2).

"2. The article of drug was shipped in interstate commerce.

"3. The drug when introduced into and while in interstate commerce was misbranded within the meaning of 21 U. S. C. 352 [502] (f) (1), in that its labeling failed to bear adequate directions for use, since the labeling did not mention the disease condition for which the drug was intended, namely, bloat in sheep and cattle, nor did it bear any directions for use for that disease.

"4. The claimant, the Globe Seed & Feed Company, Inc., is in privity with the claimant, Hy-Life Mineral Company and J. P. Rosenbaum, its owner, having obtained its title to the seized article from the Hy-Life Mineral Company and J. P. Rosenbaum.

"5. The claimants are estopped by the principle of *res judicata* from contesting the issue as to whether the drug is effective in treating or preventing bloat in livestock, this issue having been decided adversely to them in prior litigation.

"6. The drug was misbranded while held for sale after shipment in interstate commerce within the meaning of 21 U. S. C. 352 [502] (a), in that the statements in its labeling which recommended it for the prevention, treatment or cure of bloat in sheep and cattle are false and misleading.

"7. The United States of America, libellant, is entitled to summary judgment as a matter of law since there exists no genuine issue as to any material fact."

In accordance with the above findings of fact and conclusions of law, the court, on April 7, 1953, entered a decree of condemnation and ordered that the product be destroyed.

4240. Misbranding of Dr. David Roberts veterinary drugs. U. S. v. 8 Cartons, etc. (F. D. C. No. 35304. Sample Nos. 20645-L to 20650-L, incl.)

LIBEL FILED: June 16, 1953, District of Minnesota.

ALLEGED SHIPMENT: Between the approximate dates of August 8, 1951, and March 23, 1953, by Dr. David Roberts Veterinary Co., from Waukesha, Wis.

PRODUCT: 8 8-ounce cartons of *Dr. David Roberts Diuretic*, 24 1-pound, 12-ounce cartons of *Dr. David Roberts Special Rx No. 63*, 2 14-pound cartons and 4 cases, each case containing 12 3-pound cartons, of *Dr. David Roberts Herd Iron Tonik for Cows*, 8 3-pound cartons of *Dr. David Roberts Herd Iron Tonik for Sheep*, 2 3-pound cartons and 24 15-ounce cartons of *Dr. David Roberts Worm Seed Rx No. 89*, and 1 12-pound carton of *Dr. David Roberts Poultry Rx No. 62* at Duluth, Minn., together with a number of booklets entitled "The Practical Home Veterinarian," a leaflet entitled "Take Good Care of Your Livestock and Your Livestock Will Take Care of You," and a price list entitled "Full Line of Veterinary Medicines prepared by Dr. David Roberts Veterinary Co.," which accompanied the products.